UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

IN RE: BIOMET M2a MAGNUM HIP IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 2391)

CARLESE COLLINS, Plaintiff

CAUSE NO. ~~3:12-md-2391~~ 3:19cv493

SHORT FORM COMPLAINT

1. CARLESE COLLINS, Plaintiff herein and hereinafter referred to as "Plaintiff", files this Plaintiff's Original Complaint complaining of BIOMET, INC., BIOMET, LLC, and BIOMET ORTHOPEDICS, LLC (Hereinafter referred to as "BIOMET@), shows the following:

SUBJECT MATTER JURISDICTION AND VENUE

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because complete diversity exists between the parties, as Plaintiff is a citizen of Delaware, which is different from the states where Defendants are incorporated and have their principal places of business.

3. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to the claim occurred in this district where Defendants are subject to personal jurisdiction in accordance with 28 U.S.C. § 1391(c).

NATURE OF THE CASE

4. This is an action for product liability case on behalf. of Plaintiff against Defendants who were responsible for the defective The M2a-Magnum™ Large Metal Articulation System hip system implanted in Plaintiff which caused her extreme pain and suffering and subsequent revision surgery to remove the defective hip system.

PARTY DEFENDANTS

5. Upon information and belief, Defendant Biomet, Inc. is a corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M2a Magnum™ Hip System (Hereinafter referred to as "implant".) that is the subject of this lawsuit.

6. Upon information and belief, Defendant Biomet, LLC is a limited liability corporation organized and existing under the laws of the state of Indiana with its primary place of business in Warsaw, Indiana. Biomet, LLC designed, manufactured, marketed, promoted, and sold the Implant that is the subject of this lawsuit.

7. At all times mentioned, each of Biomet, Inc., Biomet LLC, and Biomet Orthopedics, LLC, was the representative, agent, employee, joint venturer, or alter ego of each of the other entities and in doing the things alleged herein was acting within the scope of its authority as such. Specifically, each Defendant was but an instrumentality or conduit of the other in the prosecution of a single venture, namely the design, promotion, and sale of the Implant. Therefore, it would be inequitable for any Defendant to escape liability for an obligation incurred as much for that Defendant's benefit as for the other.

8. Biomet, Inc., Biomet LLC, and Biomet Orthopedics, LLC, are collectively referred to herein as "Biomet."

9. Upon information and belief, at all relevant times, Defendants, committed tortuous act(s) within the state of Delaware out of which act(s) these causes of action arise.

FACTUAL BACKGROUND

The Implant Is Defective And Was Not Adequately Tested

10. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis.) In a healthy hip, both the femur and the acetabulum are strong and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

11. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical total hip replacement system consists of four separate components: (1) a femoral stem, (2) a femoral head, (3) a plastic (polyethylene) liner, and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene liner and acetabular shell.

12. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's Implant has a critical difference: it is a monoblock system which does not have an acetabular liner. Instead, the Implant forces metal to rub against metal with the full weight and pressure of the human body. Because of Biomet's defective design for the Implant, hundreds of patients - including Plaintiff - have been forced to undergo surgeries to replace the failed hip implants.

13. The Implant suffers from a design or manufacturing defect that cause excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die.

The design of the Implant was not sufficiently tested by Biomet.

14. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States, and other cities to promote the Implant. At some or all of these meetings, a representative or representatives of Biomet were present. During these meetings, Biomet assured the orthopedic surgeons, that the Implant was safe, was the best product on the market, had an excellent track record and a low and acceptable failure rate. Biomet continued to "defend" the Implant even after they became aware of numerous and serious complications with the Implant. Biomet did not reveal (and instead concealed) their knowledge of numerous and serious complications and other "bad data" during their meetings with orthopedic surgeons.

Biomet Sold the M2a Magnum™ Hip Implant To Plaintiff After It Knew It Was Defective, That It Had Injured Others, And That It Would Injure Plaintiff

15. It wasn't long after Biomet launched the Implant that reports of failures began flooding into Biomet. For example, on in August 2004, Biomet received a complaint that a patient had to undergo a surgery to remove and replace an Implant because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

16. Biomet would go on to receive hundreds of similar complaints reporting that the Implant had failed and that the failure had forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associated with the Implant have been filed with the FDA.

17. By the time Biomet sold the Implant to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associated with the Implant. Consequently, Biomet was fully aware that the Implant was defective and that dozens of patients already had been injured by that defect. Based on this information, Biomet should have recalled the Implant before it was sold to Plaintiff.

At minimum, Biomet should have stopped selling the defective implant when it became aware that it had catastrophically failed in several patients.

18. Despite its knowledge that the Implant had a defect and that it had failed hundreds of times, causing hundreds of patients to undergo the agony of another surgery, Biomet continues to sell the defective Implant. In so doing, Biomet actively concealed the known defect from doctors and patients-including Plaintiff and Plaintiffs doctor-and misrepresented that the Implant was a safe and effective medical device.

19. As numerous failures of the M2a Magnum™ Hip Implant were reported to Biomet, it continued to actively promote, market and defend the defective products. For example, Biomet published marketing brochures touting the safety and durability of metal-on- metal implants and specifically, the Implant. These brochures were given to doctors around the world, including Plaintiffs orthopedic surgeon, to encourage them to use the Implant.

20. Despite its knowledge that the Implant was defective, Biomet also made several false representations about specific design elements of the Implant that they claimed made it superior to other more safe hip implants on the market. For example, Biomet said:

- "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra-low wear rates in vivo."
- "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

21. Biomet's reason to conceal the defect in its Implant is clear. Hip implant sales are critically important to Biomet, and the Implant is one of its most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet look appealing to investors, and they ultimately were purchased by a private equity firm in 2007 for $10 billion. Biomet

was faced with a critical defect in one of its most profitable hip implant systems. The last thing Biomet wanted to do was to admit that these popular products had a critical defect that could cause a premature failure, forcing patients to have to undergo another painful surgery. Focused on corporate profits, and at the expense of patient safety, Biomet decided that it would continue to promote, market, and sell the Implant despite the fact that it knew the product was defective. To this day, Biomet continue to sell these defective implants to unsuspecting patients without any warning about the risks or the failures that have been reported to the company.

Plaintiff's Implant Was Defective and Failed, Forcing Plaintiff To Undergo An Additional Painful And Risky Surgery

22. On February 26, 2010, Plaintiff underwent a surgical procedure to implant the Implant in her right hip. By this time, Defendants had received many reports of adverse events associated with the M2a Magnum™ had been filed with the FDA and Biomet knew that the product was defective. But Biomet refused to disclose that information to Plaintiff, his physicians, or the public. Instead, Biomet misrepresented to Plaintiff and his orthopedic surgeon that the Implant was safe and effective. In reliance on these representations, Plaintiff's orthopedic surgeon made the decision to use the Implant. If it were not for the misrepresentations made by Biomet, Plaintiff's orthopedic surgeon would not have used the Implant in Plaintiff's hip replacement surgery.

23. As a result of the defective design, manufacture and composition of the Implant, and its accompanying warnings and instructions (or lack thereof), the hip implant failed, causing her severe pain.

24. On March 31, 2017, Plaintiff had a revision surgery because the acetabular cup had come loose.

25. As a direct and proximate result of the failure of his defective Implant and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including lost wages, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result, Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional minimum of this court.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

29. The running of any statute of limitation has been tolled by reason of Defendants' conduct. Defendants, through their affirmative misrepresentations and omissions, actively concealed from Plaintiff and Plaintiffs prescribing physicians the true risks associated with Biomet.

30. As a result of Defendants' actions, Plaintiff and his prescribing physician were unaware, and could not reasonably know or have learned through reasonable diligence that Plaintiff and had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the Defendant's acts and omissions.

31. Furthermore, Defendants are stopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the Implant. Defendants were under duty to disclose the true character, quality and nature of the Implant because this was non-public information which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Plaintiff, his medical providers and/or to his health facilities.

32. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose marketing and promoting a profitable medical device, notwithstanding the known or reasonably known risks. Plaintiff and medical professionals could not have afforded

and could not have possibly conducted studies to determine the nature, extent and identity of health related risks, and were forced to rely on the Defendants' representations.

FIRST CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT

33. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

34. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Implant.

35. The Implant manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

36. As a direct and proximate result of the Plaintiff's use of Defendants' Implant as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

37. Defendants' actions and omissions as alleged in this Complaint constitute a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

38. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

39. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY- DESIGN DEFECT

40. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

41. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Implant

42. The Implant, manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

43. The foreseeable risks associated with the design or formulation of the Implant, include, but are not limited to, the fact that the design or formulation of the Implant is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

44. As a direct and proximate result of the Plaintiff's use of the Implant, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendants and/or its failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic

loss in the future.

45. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

46. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

47. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY- DEFECT DUE TO NONCONFORMANCE WITH REPRESENTATIONS

48. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

49. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the Implant.

50. The Implant, manufactured and supplied by Defendants was defective in that, when it left the hands of Defendants, it did not conform to representations made by Defendants concerning the product and/or with applicable federal requirements.

51. Defendants made representations to consumers regarding the character or quality of the Implant, including but not limited to statements that the Implant was a safe and durable hip replacement system. They further asserted that the "Biomet metal-on-metal (MoM) Implant articulation system offers optimal joint mechanic restoration and ultra-low wear rates in vivo. Many studies conducted over the last several decreased have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

52. The Plaintiff and/or his physcians justifiably relied upon Defendants' representations regarding the Implant, when they selected these Biomet orthopedic products to be used in surgery.

53. As a direct and proximate result of the Plaintiffs use of the Implant, and Plaintiffs reliance on Defendants' representations regarding the character and quality of the Implant and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

54. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

55. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

56. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY - FAILURE TO WARN

57. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

58. The Implant was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiffs herein, of the dangerous risks and reactions associated with the Implant including but not limited to the risks of developing serious and dangerous side effects, including but not limited

to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the Implant, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

59. At the time of the Plaintiffs receipt and/or use of the Implant, the Implant was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

60. Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

61. Defendants, as manufacturers and/or distributors of the Implant, are held to the level of knowledge of an expert in the field.

62. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

63. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of the Implant, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity, irritation and discomfort, as well as the need for additional procedures to remove and replace the Implant, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

64. Plaintiff, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

65. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the Implant.

66. Had Plaintiff received adequate warnings regarding the risks of the Implant, she would not have used it.

67. As a direct and proximate result of the Plaintiff's use of the Implant, and Plaintiffs reliance on Defendants' representations regarding the character and quality of the Implant and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in

the future.

68. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, which warrants the imposition of punitive damages.

69. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

70. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION
NEGLIGENCE

71. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

72. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Implant into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

73. Defendants failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the Implant into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal requirements.

74. Despite the fact that Defendants knew or should have known that the Implant posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the Implant for use by consumers and/or continued to fail to comply with federal requirements.

75. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

76. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

77. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Implant when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

78. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

79. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION
BREACH OF EXPRESS WARRANTY

80. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

81. Defendants expressly warranted that the Implant was a safe and effective orthopedic device for those patients requiring a hip replacement. The Implant manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed.

82. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

83. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Implant when it knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

84. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY

85. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

86. At the time Defendants designed, manufactured, marketed, sold, and distributed the Implant for use by the Plaintiff, Defendants knew of the use for which the Implant was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

87. The Plaintiff and/or their physicians reasonably relied upon the skill and judgment of Defendants as to whether the Implant was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

88. Contrary to such implied warranty, Biomet's Implant was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

89. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

90. Defendants' conduct as described above, including but not limited to its failure to adequately design and manufacture, as well as its continued marketing and distribution of the Implant when it knew or should have known of the serious health risks it created and/or the failure to

comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages.

91. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

92. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

93. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

94. In the exercise of reasonable care, Defendants should have known that its Implant failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented the Plaintiff and/or his physicians that its device was safe and met all applicable design and manufacturing requirements.

95. The Plaintiff and/or his physicians reasonably relied to their detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. The Plaintiff and/or his physicians reasonably relied upon Defendants' representations that the Implant was safe for use.

96. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Implant, Plaintiff used Defendants' Implant and Plaintiff suffered serious physical injury, harm,

damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

97. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

98. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

99. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION
FRAUDULENT MISREPRESENTATION

100. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

101. Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiff, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

102. The representations made by the Defendants were, in fact, false.

103. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

104. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including but not limited to claims that the Implant was a safe and durable hip replacement system. They further asserted that the "Biomet metal-On- metal (MoM) Implant offers optimal joint mechanic restoration and ultra-low wear rates in vivo. Many studies

conducted over the last several decreased have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

105. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the subject product for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

106. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff was treated with the Implant, the Plaintiff was unaware of the falsity of said representations and reasonably believed them to be true.

107. In reliance upon said representations, Plaintiff was induced to, and did use the subject product, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

108. Defendants knew and were aware or should have been aware that the Implant had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

109. Defendants knew or should have known that the Implant had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently

dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

110. Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

111. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Implant, the Plaintiff used Defendants' Implant and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages.

112. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

113. Plaintiffs seek actual and punitive damages from Defendants as alleged herein.

114. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION
FRAUDULENT CONCEALMENT

115. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

116. At all times during the course of dealing between the Defendants and Plaintiff, Plaintiffs healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the subject product for its intended use.

117. Defendants knew or were reckless in not knowing that its representations were false.

118. In representations to Plaintiff, Plaintiff's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

A. The subject product was not as safe as other similar drugs and medications indicated for hip arthroplasty;

B. that the subject product was defective,

C. that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects,including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the Implant, as well as other severe and permanent health consequences, notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

D. that the subject product was manufactured negligently;

E. that the subject product was manufactured defectively;

F. that the subject product was manufactured improperly;

G. that the subject product was designed negligently;

H. that the subject product was designed defectively; and

I. that the subject product was designed improperly.

119. Defendants were under a duty to disclose to Plaintiff, Plaintiffs healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of

developing elevated metal ion levels, device failure resulting in the need. for revision surgery associated with the use of the Implant.

120. Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the Implant, including the Plaintiff, in particular.

121. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the Implant was made purposefully, willfully, wantonly, and/or recklessly, to mislead Plaintiff and Plaintiffs physicians, hospitals and healthcare providers into reliance on the use of the Implant, and to cause them to purchase, prescribe, dispense and/or use the subject product. 122. Defendants knew that Plaintiff, Plaintiffs healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

123. Plaintiff, as well as Plaintiffs doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

124. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its Implant, Plaintiff used Defendants' Implant and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

125. 125. Defendants' actions and omissions as alleged in this Complaint demonstrate a flagrant disregard for human life, so as to warrant the imposition of punitive damages.

126. Plaintiffs seek actual and punitive damages from Defendants as alleged herein

127. WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION
PUNITIVE DAMAGES

132. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

133. At all times material hereto, the Defendants knew or should have known that their Implant was inherently more dangerous with respect to the risk of significant pain, irritation, discomfort and need for additional surgeries than the alternative hip arthroplasty systems on the market.

134. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

135. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

136. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the Implant was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

137. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

138. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

139. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and his surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

140. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

141. The aforesaid conduct of Defendants was committed with knowing, conscious and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

142. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

143. WHEREFORE, Plaintiff demands judgment against Defendants on each of the above referenced claims and Causes of Action and as follows:

A. Awarding compensatory damages to Plaintiffs for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by

Plaintiff, healthcare costs, medical monitoring, together with the interest and costs as provided by the law;

B. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of Defendants who demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public. and the Plaintiffs in an amount sufficient to punish Defendants and deter future similar conduct;

C. Awarding Plaintiffs' attorney's fees;

D. Awarding Plaintiffs' the costs of the proceedings; and

E. Such other and further relief as this Court deem just and proper.

DEMAND FOR JURY TRIAL

144. The Plaintiff hereby demands a trial by jury on all counts and as to all issues.

Dated: June 20, 2019

Respectfully submitted,

Kirkendall Dwyer, LLP

By: _____

Alexander G. Dwyer
Texas State Bar No. 24054271
440 Louisiana St. Ste 1901
Houston, Texas 77002
214-271-4027Telephone
214-253-0629Facsimile

ATTORNEY FOR PLAINTIFF